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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,427	02/25/2004	Alberto Mantovani	2818-199	1336

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EXAMINER

MONDESI, ROBERT B

ART UNIT PAPER NUMBER

1653

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/785,427

Applicant(s)

MANTOVANI, ALBERTO

Examiner

Robert B. Mondesi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. **Claims 1-3 and 8** drawn to a method of increasing or decreasing the reproductive ability in a female subject comprising increasing or decreasing the amount of activity of PTX3 in the cumulous oophorous and or extracellular matrix of cumulous oophorus comprising the administering of a viral or plasmid vector containing a nucleic acid sequence encoding a human PTX or a functional fragment thereof or a modulator of PTX3 , classified in class 514, subclass 14.
- II. **Claims 4-5**, drawn to a method of increasing or decreasing the reproductive ability in a female subject comprising increasing or decreasing the amount of activity of PTX3 in the cumulous oophorous and or extracellular matrix of cumulous oophorus comprising the administering of a PTX or a or a functional fragment thereof wherein the administering comprises local administration, classified in class 514, subclass 12.
- III. **Claim 6**, drawn to a method of assessing the reproductive ability of a female subject comprising the measuring or detecting the presence of PTX3 protein in said female subject as a diagnostic marker of reproducibility of said female, classified in class 435, subclass 7.1.

- IV. **Claim 7**, drawn to a method of screening a pharmaceutical compound to assess the capability of said compound to affect the reproductive ability in a female subject comprising measuring or detecting the ability or effectiveness of said compound to increase or decrease the presence or activity of pTX3 expressed from granulosa cells, or measuring or detecting the ability or effectiveness of said compound to bind or inhibit the binding of PTX3 to a target receptor or function, classified in class 435, subclass 7.1 .
- V. **Claims 9 and 10**, drawn to a pharmaceutical composition comprising a modulator of long pentaxrin PTX3 activity, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II, I and III, I and IV, II, and III, III and IV are unrelated.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, and different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects, the invention of Group I is a method of increasing or decreasing the reproductive ability in a female subject comprising increasing or decreasing the amount of activity of PTX3 in the cumulous oophorous and or extracellular matrix of cumulous oophorus comprising the administering of a viral or plasmid vector containing a nucleic acid sequence encoding a human PTX or a functional fragment thereof or a modulator of PTX3, the invention of

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Group II is a a method of increasing or decreasing the reproductive ability in a female subject comprising increasing or decreasing the amount of activity of PTX3 in the cumulous oophorous and or extracellular matrix of cumulous oophorus comprising the administering of a PTX or a or a functional fragment thereof wherein the administering comprises local administration, a method of assessing the reproductive ability of a female subject comprising the measuring or detecting the presence of PTX3 protein in said female subject as a diagnostic marker of reproducibility of said female, whereas the invention of Group IV a method of screening a pharmaceutical compound to asses the capability of said compound to affect the reproductive ability in a female subject comprising measuring or detecting the ability or effectiveness of said compound to increase or decrease the presence or activity of pTX3 expressed from granulose cells, or measuring or detecting the ability or effectiveness of said compound to bind or inhibit the binding of PTX3 to a target receptor or function.

Inventions II and V, III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a materially different process such as the process of producing anti-bodies.

The product of the invention of Group V is not used in the method of the inventions of Groups I and IV.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

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dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, search and divergent subject matter restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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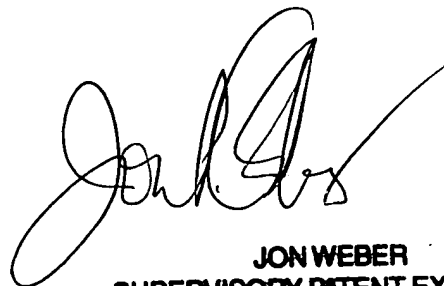
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Robert B. Mondesi


07-09-05



JON WEBER
SUPERVISORY PATENT EXAMINER